



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. FDA-2016-F-1805]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because this use has been abandoned. This action is in response to a petition filed by Keller and Heckman LLP on behalf of the Society of the Plastics Industry, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written objections and requests for a hearing on the final rule by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See the ADDRESSES section, and SUPPLEMENTARY INFORMATION section VIII of this document, for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The <https://www.regulations.gov> electronic filing system will accept

comments until midnight Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-F-1805 for "Indirect Food Additives: Polymers." Received objections, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vivian Gilliam, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1193.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the Federal Register of June 30, 2016 (81 FR 42585), we announced that we filed a food additive petition (FAP 6B4816) submitted on behalf of Society of the Plastics Industry, Inc. (SPI) by Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. The petition proposed to amend § 177.1210 (21 CFR 177.1210) to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because the use has been intentionally and permanently abandoned.

In response to food additive petitions filed in 1962, FDA authorized the use of 66 substances, including potassium perchlorate, for the use in manufacturing closure-sealing gaskets under § 177.1210 (27 FR 7092, July 26, 1962).

II. Evaluation of Abandonment

Section 409(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(i)) states that we shall, by regulation, establish the procedure for amending or repealing a food additive regulation, and that this procedure shall conform to the procedure provided in section 409 of the FD&C Act. Our regulations specific to administrative actions for food additives provide that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive (§ 171.130(a) (21 CFR 171.130(a))). These regulations further provide that any such petition must include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data submitted as a food additive petition must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting such petitions (§ 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete and permanent for any intended uses in the U.S. market. Although section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on the safety of the food additive. Instead, the amendment or revocation is based on

the fact that regulatory authorization is no longer necessary because the use of the food additive has been permanently and completely abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories) or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The present petition includes the following information to support the claim that the use of potassium perchlorate as a food additive in closure-sealing gaskets for food containers has been abandoned in the U.S. market: (1) None of the companies that originally petitioned for the inclusion of potassium perchlorate in § 177.1210 use potassium perchlorate for food-contact applications in the United States; (2) the sole domestic manufacturer of potassium perchlorate does not market the substance into food contact applications in the United States; (3) the major domestic manufacturers of gaskets do not use potassium perchlorate in the manufacture of their products; and (4) none of the member companies, which include domestic and international companies, surveyed by SPI indicated that they had any knowledge or reason to believe that potassium perchlorate was being used in closures with sealing gaskets for food containers.

First, the petition provided information to show that the original petitioners who filed the food additive petitions that resulted in the listing of potassium perchlorate in § 177.1210 do not use potassium perchlorate for food-contact applications in the United States. The petition stated that three of the original four companies that filed the food additive petitions that resulted in the

listing for potassium perchlorate in § 177.1210 are still operating, and that the division of the fourth company that participated in the original petition is no longer in business. The petitioner surveyed the remaining three companies (or their appropriate successor(s) in interest) about their use of potassium perchlorate in closures with sealing gaskets for food containers and asked them to verify that they do not: (1) Currently manufacture potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States; (2) currently import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States; (3) intend to manufacture or import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the United States in the future; or (4) currently maintain any inventory of potassium perchlorate for sale or distribution into commerce that is intended to be marketed for use as a component of closures with sealing gaskets for food containers in the United States. The petition included signed letters from the three companies confirming agreement with these four points.

Second, the petition asserted that American Pacific Corporation, Western Electrochemical Company (AMPAC) is the sole known domestic manufacturer of potassium perchlorate and provided information to show that AMPAC does not market the substance for food contact applications in the United States. Specifically, the petition included a signed letter from AMPAC stating that it does not manufacture, import, or maintain any inventory of potassium perchlorate for sale or distribution for use in closures with sealing gaskets for food containers in the United States. In addition, AMPAC provided supplemental information stating that, to the best of its knowledge, AMPAC is the sole domestic manufacturer of potassium perchlorate in the United States.

Third, the petition provided information to show that the major domestic manufacturers of gaskets do not use potassium perchlorate in the manufacture of their products. The petition stated that SPI conducted research to identify all major U.S.-based manufacturers of closures with sealing gaskets for food containers. The petition further stated that SPI contacted each manufacturer identified by its research, and that each company confirmed to SPI that it does not use potassium perchlorate in the manufacture of gaskets for food contact materials, and that potassium perchlorate may never have been used for this purpose. According to the petition, these manufactures believe that they represent the substantial majority of gasket production, not only domestically, but globally as well.

Fourth, the petition stated that SPI surveyed the 53 companies in its Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC). According to the petition, the FDCPMC companies represent the full range of the packing supply chain of plastic food-contact material manufacturers and their raw material suppliers, and they include international companies with affiliates throughout the world. The petition stated that the survey asked the companies to advise whether they had any actual knowledge or reason to believe that "potassium perchlorate is being manufactured, used, distributed, or imported into the U.S. for use in the manufacture of closures with sealing gaskets for food-contact applications." No company responded that it had any knowledge or reason to believe that potassium perchlorate was being used in closures with sealing gaskets for food containers. Moreover, the petition stated that, in its effort to gather supporting information, the petitioner was unable to identify any company with memory of, or records indicating, that potassium perchlorate had ever been used commercially as a component of closures with sealing gaskets.

III. Comments on the Filing Notification

We provided 60 days for comments on the filing notification. We received two comments. For ease of reading, we preface each comment discussion with a numbered "Comment," and the word "Response" appears before FDA's response. The number assigned is for organizational purposes only and does not signify any individual comment's value, importance, or order in which it was received.

(Comment 1) The comment requested that we not make a final decision on the petition until after we make a final decision on the petition (FAP 4B4808) submitted in 2014 by Natural Resources Defense Council et al. (Docket No. FDA-2015-F-0537), asking us to remove certain authorizations, including the use of potassium perchlorate that is the subject of this petition. The comment stated that we are statutorily required to regulate food additives and prevent the use of those that are unsafe and that FDA's failure to make a determination based on safety would fall short of FDA's statutory duty. The comment stated that if we make a decision on the petition based on abandonment before making a decision on FAP 4B4808 based on safety, a company may conclude that the use of potassium perchlorate in closures with sealing gaskets for food containers is generally recognized as safe (GRAS) without notifying us. The comment also stated that making a decision on the abandonment petition first encourages industry to only consider whether a use of a food additive has been abandoned in order to preempt a safety decision.

(Response) FDA disagrees. We are not required to make a final decision on FAP 4B4808 before the current petition. With regard to the assertion that FDA is required to make a safety determination, FDA has numerous responsibilities related to food additives. Each year, FDA receives and responds to hundreds of submissions under the various petition and notification programs it administers. Therefore, if the use of a food additive is no longer

authorized in response to an abandonment petition, FDA may determine that it is neither necessary nor an efficient use of its limited resources to address safety arguments related to an abandoned use.

With regard to the comment's concern that a manufacturer may conclude that the use of potassium perchlorate in closures with sealing gaskets for food containers is GRAS without notifying us, we note that, for a substance to be GRAS based on scientific procedures, the scientific data and information about the use of a substance must be generally available and there must be general recognition among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use (§ 170.30). Prior approval as a food additive does not necessarily mean that the use of a substance is GRAS (see 81 FR 54960 at 54976, August 17, 2016). FDA encourages firms to seek our evaluation of any conclusion of GRAS status before they introduce the substance into the market. In the event that, after the authorization in § 177.1210 has been removed based on abandonment, a manufacturer later wishes to use potassium perchlorate for this intended use, we would expect the manufacturer to seek re-authorization through submission of a food contact notification or food additive petition because this intended use was previously authorized under section 409 of the FD&C Act.

With regard to the assertion that an abandonment petition could be used by industry to preempt a safety determination by FDA, we have the discretion to make a safety determination regardless of whether there is an abandonment petition.

(Comment 2) The comment stated that SPI has not considered overseas use and manufacturing of potassium perchlorate in closures with sealing gaskets for food containers. The comment indicated that SPI had not provided sufficient assurances that the uses of potassium perchlorate had been abandoned.

(Response) FDA disagrees. According to the petition, SPI gathered information about the use of potassium perchlorate used in closures with sealing gaskets for food containers from its member companies, which include international companies with affiliates throughout the world, and from major domestic manufacturers of gaskets, and these manufacturers believe that they represent the substantial majority of gasket production, not only domestically, but globally as well. None of the companies surveyed reported that they had any reason to believe that potassium perchlorate is used to make closures with sealing gaskets for food containers. We note that the comment did not provide information to show that this use has not been abandoned.

In addition, when we publish a notice of filing of a food additive petition, we notify the World Trade Organization (WTO) of the FAP filing. The WTO provides notice of the potential action (in this case, the removal of authorization for potassium perchlorate in § 177.1210 based upon abandonment) to the WTO contact point for each WTO member country. The WTO contact point for each country distributes the notices to the relevant regulatory agencies and industry bodies within that country. If the proposed action affects a member country's trade of affected products, it would provide comment to the WTO notice by commenting to the appropriate docket established for the petition. We did not receive any comments to the WTO notice on the filing of this petition.

IV. Conclusion

We reviewed the data and information in the petition and other available relevant material to determine whether the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers has been permanently and completely abandoned. Based on the available information, we conclude that the use of potassium perchlorate has been abandoned for use as an additive in closure-sealing gaskets for food containers. Therefore, we are amending

part 177 as set forth in this document to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers.

Because the authorization for this intended use has been removed from § 177.1210 based on abandonment, we do not anticipate that industry will resume this intended use in the future. In the event that, after the authorization in § 177.1210 has been removed based on abandonment, a manufacturer later wishes to use potassium perchlorate for this intended use, we would expect the manufacturer to seek re-authorization through submission of a food contact notification or food additive petition because this intended use was previously authorized under section 409 of the FD&C Act.

V. Public Disclosure

In accordance with § 171.1(h), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the Federal Register of June 30, 2016, notice of petition for FAP 6B4816. We stated that we had determined, under 21 CFR 25.32(m), that this action "is of a type that does not individually or cumulatively have a significant effect on the human environment," such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 177 is amended as follows:

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1210 [Amended]

2. In § 177.1210, in paragraph (b)(5), in table 1, remove the entry for "Potassium perchlorate."

Dated: April 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-08988 Filed: 5/3/2017 8:45 am; Publication Date: 5/4/2017]